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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,556	05/07/2002	David Graham Little	RICE-006	7597

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EXAMINER	
KANTAMNENI, SHOBHA	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,556	LITTLE, DAVID GRAHAM	
	Examiner	Art Unit	
	Shobha Kantamneni	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *48-53,63-66,73,74,79 and 80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *NONE* is/are allowed.

6)☒ Claim(s) *48-53,63-66,73,74,79 and 80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02/03/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the applicant's response filed on 01/03/2006, wherein claims 48-53, 63-66, and 73-74, and 79-80 have been amended.

Upon further consideration, and in view of new ground(s) of rejection the rejections made in the non-final office action dated 08/06/2004 are herein withdrawn.

Claims 48-53, 63-66, 73-74, and 79-80 are examined herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 48-53, 63-66, 73-74, 79-80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "a subject" renders these claims indefinite. The recitation "a subject" is not clearly defined in the claims or specification. One of ordinary skill in the art could not ascertain and interpret the metes and bounds of the patent protection desired as to what "a subject" would be, for example, that the term "subject" would be a any biological system, an animal or a human, or any non-biological system. Thus, one of ordinary skill in the art could not ascertain and interpret encompassed thereby.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 48-52, 63-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Yates (US 5,646,134, PTO-892).

Yates discloses a method for promoting bone growth at a fracture site comprising administering bisphosphonate to a patient. See column 1, lines 33-38; column 2, lines 64-67; column 4, lines 10-14; column 6, EXAMPLE. It is disclosed that the bisphosphonate can be administered to the periprosthetic bone area systemically either orally as tablets and/or parenterally, including subcutaneous or intravenous injection, or can be delivered in a slow release form. The bisphosphonate can be administered locally to the specific periprosthetic area in need of bone growth or repair. See column 3, lines 54-66. It is also taught that the bisphophonates can be administered by coating the orthopedic implants at the time of the implant operation i.e at an early stage of the treatment of fractured bone or near the time of surgery. See column 4, lines 14-16. An effective dose of bisphophonate is about 1.5 to 3000 μg/kg per day of body weight. Effective doses for local administration are about 0.001 μg to 1 mg per application site. See column 5, lines 1-5.

Thus Yates anticipates the instant claims 48-52, 63-64.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 48-53, 63, 73, and 79 are rejected under 35 U.S.C. 102(a) as being anticipated by Ke et al. (US 6,352,970, PTO-892).

Ke et al discloses that Zoledronate, the specific bisphosphonate of claim 73 at column 5, lines 22-34 is capable of treating bone fractures. The mode, dosage as a single dose, site, time and regiments of administration of claims 49-53 are taught at column 16, lines 13-64, column 17, lines 1-25 and lines 40-55. It is taught that the administration can be done in a regiment to the site as determined by the patients needs. The dosage of bisphosphonates is from about 0.1 to 10 mg/kg/day. See column 15, lines 28-33. The reference also discloses that administration of zoledronate can be transdermal, intravenous or oral routes. See column 17, lines 1-7.

With respect to the recitation "a method for promoting bone growth at a fracture site", Ke's method will inherently promote bone growth at a fracture site, since the method steps are same as instantly claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 48-50, 52-53, 63-66, 74, and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by GEDDES (WO 93/11786, PTO-1449).

Geddes et al. disclose a method of increasing bone mass in a human afflicted with osteoporosis comprising administering a bisphosphonate administration regimen. See abstract; page 20, lines 13-27. It is disclosed that the bisphophonate is administered at least 1 day of every thirty day period i.e about 4 to 6 weeks after the initial dose. See page 5, lines 25-31. It is also taught that the therapeutic regimen comprising bisphosphonate is administered for at least about twelve months or until a net skeletal mass is obtained. See page 25, lines 8-15. It is taught that the treatment regimen can comprise a combination of two or more bisphosphonates. See pages 20-22. Bisphosphonates can be administered orally as a tablet containing 0.002 mgP/kg per day, in a unit-dosage form. Administration of bisphosphonates by intraperitoneal, intravenous, parenteral, transdermal routes is also disclosed. See page 25, and page 27, bottom paragraph. It is disclosed that when a human, African-American male with a history of atraumatic fractures was administered once a week with bisphosphonate, 4-amino-1-hydroxy-1,1-bisphosphonic acid, orally as a tablet containing 0.03 mgP/kg per day, demonstrated an increase in 14.5 mg/cc spinal bone mineral, and no further atraumatic fractures were observed. See page 29, EXAMPLE 2.

With respect to the recitation "a method for promoting bone growth at a fracture site", Gedde's method will inherently promote bone growth at a fracture site, since the method steps are same as instantly claimed.

Thus Geddes anticipates the instant claims 48-50, 52-53, 63-66, 74, and 80.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 48-51, and 63-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Goodship et al. (Annals of Oncology 5 (Suppl 7), S53-S55, 1994, PTO-1449).

Goodship et al. disclose a method of fracture repair in ovine bone by administering bisphosphonate, pamidronate. See page S53. It is disclosed that the adult female Welsh sheep are given pamidronate 0.5 mg/kg in 250 ml saline as a slow intravenous infusion over 1 hr once a week for 4 weeks prior to osteotomy, and for 12 weeks postoperatively. See page S53, right hand column. The rate of increase in bone mineral was 76 % greater in the sheep administered with pamidronate than in the controls. See Fig. 2, page S 54.

Thus, Goodship et al. anticipate instant claims 48-51, and 63-64.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Friday, 7.30am-3.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, Ph.D can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni, Ph.D
Patent Examiner
Art Unit : 1617

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER